TABLE OF EXEMPT PRESCRIPTION PRODUCTS—Continued

Company	Trade Name	NDC Code	Form	Controlled Substance	(mg or mg/ml)
Winthrop Labs	Isuprel	00024–0874	EL	Phenobarbital	0.40
Zenith Labs Inc	Azpan	00172–3747	TB	Phenobarbital	8.00

[52 FR 9803, Mar. 27, 1987, as amended at 53 FR 10861, April 1, 1988; 54 FR 11520, Mar. 21, 1989; 55 FR 9114, Mar. 12, 1990; 57 FR 23301, June 3, 1992]

EXEMPT ANABOLIC STEROID PRODUCTS

§ 1308.33 Exemption of certain anabolic steroid products; application.

(a) The Administrator, upon the recommendation of the Secretary of Health and Human Services, may, by regulation, exempt from the application of all or any part of the Act any compound, mixture, or preparation containing an anabolic steroid as defined in § 1308.02 if, because of its concentration, preparation, mixture or delivery system, it has no significant potential for abuse (Pub. L. 101–647 section 1903(a)).

(b) Any person seeking to have any compound, mixture, or preparation containing an anabolic steroid as defined in § 1308.02 exempted from the application of all or any part of the Act, pursuant to paragraph (a) of this section, may apply to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(c) An application for an exemption under this section shall be submitted in triplicate and contain the following information:

(1) The name and address of the applicant;

(2) The name of the product;

(3) The chemical structural formula or description for any anabolic steroid contained in the product;

(4) The complete description of dosage and quantitative composition of the dosage form;

(5) A description of the delivery system, if applicable;

(6) The indications and conditions for use in which species, including whether or not this product is a prescription drug;

(7) Information to facilitate identification of the dosage form, such as shape, color, coating, and scoring;

(8) The label and labeling of the immediate container and the commercial containers, if any, of the product;

(9) The units in which the dosage form is ordinarily available; and

(10) The facts which the applicant believes justify:

(i) A determination that the product has no significant potential for abuse and

(ii) a granting of an exemption under this section.

(d) Within a reasonable period of time after the receipt of the application for an exemption under this section, the Administrator shall notify the applicant of his acceptance or nonacceptance of the application, and if not accepted, the reason therefor. The Administrator need not accept an application for filing if any of the requirements prescribed in paragraph (c) of this section is lacking or is not set forth so as to be readily understood. The applicant may amend the application to meet the requirements of paragraph (c) of this section. If accepted for filing, the Administrator will request from the Secretary for Health and Human Services his recommendation, as to whether such product which contains an anabolic steroid should be considered for exemption from certain portions of the Controlled Substances Act. On receipt of the recommendation of the Secretary, the Administrator shall make a determination as to whether the evidence submitted or otherwise available sufficiently establishes that the product possesses no significant potential for abuse. The Administrator shall issue and publish in the FEDERAL REGISTER his order on the application, which shall include a reference to the legal authority under which the order is issued, and the findings of fact and conclusions of law upon which the order is based. This order shall specify

the date on which it will take effect. The Administrator shall permit any interested person to file written comments on or objections to the order within 60 days of the date of publication of his order in the FEDERAL REGISTER. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

(e) The Administrator may revoke any exemption granted pursuant to section 1903(a) of Public Law 101–647 by following the procedures set forth in paragraph (d) of this section for handling an application for an exemption which has been accepted for filing.

[56 FR 42936, Aug. 30, 1991; 57 FR 10815, Mar. 31, 1992]

§ 1308.34 Exempt anabolic steroid products.

The following anabolic steroid containing compounds, mixtures, or preparations have been exempted by the Administrator from application of sections 302 through 309 and 1002 through 1004 of the Act (21 U.S.C. 822–829 and 952–954) and §§ 1301.24, 1301.31, 1301.32, and 1301.71 through 1301.76 of this chapter for administrative purposes only:

TABLE OF EXEMPT ANABOLIC STEROID PRODUCTS

Trade name	Company	NDC No.	Form	Ingredients	Quantity
Androgyn L.A.	Forest Pharmaceuticals, St. Louis, MO.	0456–1005	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
Andro-Estro 90–4	Rugby Laboratories, Rockville Centre, NY.	0536–1605	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
depANDROGYN	Forest Pharmaceuticals, St. Louis, MO.	0456–1020	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
DEPO–T.E.	Quality Research Pharm., Carmel, IN.	52765–257	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
depTESTROGEN	Martica Pharmaceuticals, Phoenix, AZ.	51698–257	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Duomone	Wintec Pharmaceutical, Pacific, MO.	52047–360	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
DURATESTRIN	W.E. Hauck, Alpharetta, GA.	43797–016	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
DUO–SPAN II	Primedics Laboratories, Gardena, CA.	0684–0102	Vial	Testosterone cyplonate Esterified cypionate	50 mg/ml 2 mg/ml
Estratest	Solvay Pharmaceuticals, Marletta, GA.	0032–1026	TB	Esterified estrogens Methyltestosterone	1.25 mg 2.5 mg
Estratest HS	Solvay Pharmaceuticals, Marletta, GA.	0032–1023	TB	Esterified estrogens Methyltestosterone	0.625 mg 1.25 mg
PAN ESTRA TEST	Pan American Labs, Covington, LA.	0525–0175	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Premarin with Methyltestosterone.	Ayerst Labs. Inc., New York, NY.	0046–0879	TB	Conjugated estrogens Methyltestosterone	1.25 mg 10.0 mg
Premarin with Methyltestosterone.	Ayerst Labs. Inc., New York, NY.	0046–0878	TB	Conjugated estrogens Methyltestosterone	0.625 mg 5.0 mg
Synovex H Pellets in process.	Syntex Animal Health, Palo Alto, CA.		Drum	Testosterone propionate. Estradiol benzoate	25 mg. 2.5 mg.
Synovex H Pellets in process granulation.	Syntex Animal Health, Palo Alto, CA.		Drum	Testosterone propionate. Estradiol benzoate	10 parts. 1 part.
TEST–ESTRO Cypionates.	Rugby Laboratories, Rockville Centre, NY.	0536–9470	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testagen	Clint Pharmaceuticals, Nashville, TN.	55553–257	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml. 2 mg/ml.
Testosterone Cyp 50 Estradiol Cyp 2.	I.D.E.-Interstate, Amityville, NY.	0814–7737	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml